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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,795	12/06/2001	John P. Morseman	031676.0263	8799
21967	7590	07/30/2003		
HUNTON & WILLIAMS INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER	CEPERLEY, MARY
		ART UNIT	PAPER NUMBER	1641

DATE MAILED: 07/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/889,795	MORSEMAN ET AL.
	Examiner	Art Unit
	Mary (Molly) E. Ceperley	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: |

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1) Although the restriction requirement of record is believed to be proper for the reasons set forth in paragraph **2)** of the January 27, 2003 Office action, the restriction requirement is hereby withdrawn in view of the fact that a search of all claims was not unduly burdensome. Claims 1-7 have been examined in the merits in this Office action.

2) In claim 5.b. and claim 7, line 2, the spelling of the term "activating" (first occurrence) should be corrected.

3) **Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.**

4) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enabling written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) There is no descriptive support in the specification for the term "activating reagent" used in the claims (see claims 5 and 7). Although page one of the specification, **Review of Related Art**, describes the conventional use of NHS compounds in combination with

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carbodiimides (CDI) to form NHS esters, and page nine, lists appropriate **Types of NHS** and **Types of water soluble carbodiimides**, there is no indication in the specification of what component(s) are required constituents of the "activating reagent".

b) In claim 1, the term "a label containing an amine or a carboxyl group" is inconsistent with the enabling written description of the invention of page 8, lines 1-8, of the specification wherein it is indicated that a "carboxyl group" on the "label" is required whereas the presence of an "amine group" is undesirable ("preferably the label moiety does not have free amines"). For all claims, enablement is present only for the use of "labels" which contain carboxyl groups.

c) There is no enabling written description in the specification to support the method of claim 5, in particular step d., "removing the activating reagent in the presence of a target moiety", whereby the target moiety is conjugated to the label". Further, it is not clear that "removing the activating reagent" would cause the "target moiety" to be conjugated to the "label".

d) There is no enabling written description in the specification to support the generic concept of claim 6. Specifically, support in the specification is limited to the method described at page 5, lines 21-31 which uses SMCC and specific "reductants". Further, page 8, **Types of labels**, indicates that amine functions on the label are undesirable (inconsistent with claim 6.a., "derivatizing a label containing primary or secondary amines"). Further, it is unclear what moiety the "reductant" reduces.

e) There is no enabling written description in the specification to support the method of claim 6, in particular step d., "removing the reductant in the presence of a target moiety", whereby the target moiety is conjugated to the label". Further, it is not clear that "removing the reductant" would cause the "target moiety" to be conjugated to the "label".

f) The specification fails to define the word "target". The enabling written description in the specification is limited to description of page 4, lines 7-9.

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7) Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 2 is confusing and incomplete for the reason that although the claim is drawn to "a method for conjugating label to target moiety", there is no step wherein the "target moiety" is added.

b) In claim 5, step b., it is unclear what is meant by the term "its reaction partner". To what does the term "its" refer? What is the "reaction partner" and what does it react with? See also, claim 7.

c) In claim 5, step c., there is no antecedent basis for the term "label". Is the term "derivatized label" intended?

d) In claim 5, step b., it is unclear what type of "activation" occurs (i.e. activated toward what type of reaction?). There is no requirement that the "activating agent" activate for the purpose of attaching the "target moiety". See also, claim 7.

e) It is unclear what components are meant to be included by the term "activating agent" and what type of "activation" is intended.

f) It is unclear what the "reductant" of claim 6. b. reduces.

g) It is unclear what is meant by the term "target moiety" as it is used in the claims.

h) In claim 6.b., it is unclear whether either the "maleimide derivatized label" or the "reductant" or both are required to be "in dry form".

8) Hendriks et al (U.S. 2003/0035786 A1), paragraphs [0065], [0077], and [0078], is cited to further show the state of the art.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 29, 2003

Mary E. Ceperley
Mary E. (Molly) Ceperley
Primary Examiner
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